Fecal Bacteriotherapy

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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FECAL BACTERIOTHERAPY (cont.)

Description:

Clostridium difficile, also referred to as C. difficile and C. diff, is part of the normal balance of bacteria living in the intestines. Most individuals never experience any problems with C. difficile. However, if the normal balance of bacteria in the intestines is disrupted, C. difficile can become established in the colon and may begin to grow out of control. Disruption of the normal colonic flora occurs most commonly following administration of oral, parenteral or topical antibiotics. Symptoms of C. difficile infection (CDI) include diarrhea, abdominal pain, severe inflammation of the colon (colitis), fever, an elevated white blood cell count, vomiting and dehydration. In severely affected individuals, the inner lining of the colon can become severely inflamed (pseudomembranous colitis) with the potential to perforate.

Fecal bacteriotherapy, also known as fecal microbiota transplantation or FMT and intestinal microbiota transplantation, is a CDI treatment to replace damaged and/or disordered native microbiota with a stable community of donor microorganisms.

Fecal bacteriotherapy involves the infusion of intestinal microorganisms via transfer of stool from a healthy individual into a diseased individual to restore normal intestinal flora. An upper gastrointestinal endoscopy with optical endomicroscopy is performed to obtain and prepare the specimen for transplant. The stool can be infused as a liquid suspension into the diseased individual’s upper gastrointestinal tract through a nasogastric tube or gastroscopy or into the colon through a colonoscope or rectal catheter.

Fecal bacteriotherapy has also been investigated in the treatment of constipation, inflammatory bowel disease, irritable bowel syndrome, disorders and metabolic syndrome and pouchitis.

Criteria:

- Fecal bacteriotherapy for the treatment of recurrent clostridium difficile infection is considered medically necessary with documentation of ALL of the following:
  1. At least three episodes of recurrent infection
  2. Episodes are refractory to appropriate antibiotic regimens, including at least one regimen of pulsed vancomycin
Fecal bacteriotherapy (cont.)

Criteria: (cont.)

- Fecal bacteriotherapy for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, but are not limited to:

- Constipation
- Inflammatory bowel disease
- Irritable bowel syndrome
- Metabolic Syndrome
- Pouchitis

Resources:

Literature reviewed 12/13/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

FECAL BACTERIOThERAPY (cont.)

Resources: (cont.)


Fecal Bacteriotherapy (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit’éego bina’idilkidgo éí doodgo Háida bíí’ anilyeedígíí t’aadoo le’e yina’idilkidgo beehaz’áanii hólo díí t’aá hazaadk’ehíí háká a’doo wolgo bee haz’a doo bąq’ halné’iíi kojí bich’é’ hodilíihíí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساعدوه أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية. يُغنى عن دوم ابيكلفة للمتحدث مع مترجم اتصل ب 877-475-4799.
Fecal Bacteriotherapy (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuhang tulong at impormasyon sa iyong wika ng walang gastos. Upang makinusap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 무상이 없을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화해주세요.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

بگذار، اگر شما یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعاتی که به زبان خود خواهید در سوالات نماید، 877-475-4799 می‌کنند.

Assyrian:

بگذار، اگر شما یا کسی که شما به آن کمک می‌کنید، سوال در مورد اطلاعاتی که به زبان خود خواهید در سوالات نماید، 877-475-4799 می‌کنند.


Thai: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถขอความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยโทรศัพท์ โทร. 877-475-4799.